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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/682,249	08/09/2001	Guerry L. Grune		1874

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VIRGINIA BEACH, VA 23452

EXAMINER

LAMM, MARINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/682,249

Applicant(s)

GRUNE, GUERRY L.

Examiner

Marina Lamm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 12-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (Claims 1-11 and 25-27) in Paper No. 3 is acknowledged. The traversal is on the ground(s) that the invention represents a single inventive concept (i.e. non-endocrine disrupting, cytoprotective, immuno-enhancing sunblock). This is not found persuasive because the invention of Groups I, II and III are unrelated. The Claims of Groups II and III are directed to using compositions different from the composition of Group I. The compositions recited in Groups II and III have additional ingredients that impart additional and/or different properties to the composition of Group I and require different search.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Objections

2. Claims 26 and 27 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Accordingly, the claims 26 and 27 have not been further treated on the merits.

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The

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filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claim 25 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 15 of prior U.S. Patent No. 5,980,871. This is a double patenting rejection.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1 and those dependent thereon are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 recites the limitation "non-endocrine disrupting sunscreen agent". These "non-endocrine disrupting sunscreen" agents are not described in the specification; there is no guidance as to how to select sunscreens that are "non-endocrine disrupting" among the variety of available sunscreens; the specification does not provide any examples of these sunscreens. In view of the above, it is the Examiners position that one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 1-11, 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 26 recite the broad recitation "a carrier oil", and the claims also recite "preferably an essential oil" which is the narrower statement of the range/limitation. Similarly, Claim 11 recites the limitations "preferably an immuno-responsiveness factor (IRF) of greater than zero" and "preferably a non-endocrine disrupter (NED) factor not greater than zero".

Claim 4 is viewed as indefinite because it recites the limitation "wherein active sun-blocking and sunscreen agents, emollients, and carrier oils may include other non-endocrine disruptive agents consisting of a sunless tanning agent, an antimicrobial agent,..." It is unclear

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what is meant by said phrase. Further, Claim 4 recites improper Markush language "consisting of". The proper Markush claim language is "selected from the group consisting of".

Claims 5 and 6 recite the limitation "said inorganic sunscreen agent" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim because Claim 1 recites "inorganic sun-blocking agent".

Claims 5-11 recite the limitation "a sunscreen composition". There is insufficient antecedent basis for this limitation in the claim because Claim 1 recites "a composition". Similarly, Claim 26 recites the limitation "a UV-protective composition". There is insufficient antecedent basis for this limitation in the claim because Claim 1 recites "a composition".

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 4-10 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lukenbach et al. (US 5,980,871).

Lukenbach et al. teach sunscreen compositions containing from about 2 to about 25% of an inorganic sunscreen agent such as titanium dioxide having a particle size of less than about 300 nm, zinc oxide or mixtures thereof, from about 0.5 to about 10% of an anionic emulsifier such as sodium stearate, and from about 0.5 to about 10% of an oil component comprising a carrier oil and an emollient. See Claim 16; col. 5, lines 15-67; col. 6, lines 1-36. The ratio of inorganic sunscreen agent to oil component is from about 0.3:1 to about 1:1. See

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Claim 27; col. 6, lines 37-40. The Lukenbach's compositions have a pH of above 5 and SPF of at least 10. See Claims 12-14; col. 6, lines 46-54. The compositions may additionally contain antimicrobial agents, depigmenting agents, anti-aging agents, etc. See col. 6, lines 61-65; Claim 19. Lukenbach et al. teach a method of making a sunscreen composition comprising (a) adding deionized water to a vessel; (b) heating the water; (c) adding a carrier oil and an anionic emulsifier to the vessel; (d) slowly adding an inorganic sunscreen agent to said vessel and heating and mixing said resultant composition; and (e) adjusting the pH of said composition to above 5. See Claim 15.

Thus, Lukenbach et al. teach each and every limitation of Claims 1, 4-10 and 25-27.

11. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Wenker (US 5,972,362) in view of Strickland et al. (US 5,824,659).

Wenker teaches skin care compositions containing 17-19% of Aloe Vera gel, 0-0.5% of titanium dioxide as well as beeswax, glycerin, tincture of iodine and other conventional ingredients. See col. 2, lines 6-15. With respect to the limitation "said compositions capable of protecting skin from harmful effects of radiation including ultraviolet light or sunlight", this limitation is inherent in the Wenker reference. Thus, Strickland et al. teach that aloe Vera (aloe barbadensis Miller) extracts are useful to protect skin from damaging effects of UV radiation. See col. 1, lines 10-14; Claim 1.

Thus, Wenker teaches each and every limitation of Claims 1-6.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Lukenbach et al. in view of Strickland et al.

Lukenbach et al. teach sunscreen compositions as discussed above.

Lukenbach et al. do not teach aloe of the instant claims.

However, Strickland et al. teach that aloe Vera (aloe barbadensis Miller) extracts are useful to protect skin from damaging effects of UV radiation as discussed above.

One of ordinary skill would have been motivated to employ aloe extract of Strickland et al. in sunscreen compositions of Lukenbach et al. with a reasonable expectation of beneficial results such as additional protection of the skin against UV light.

14. Claim 11 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lukenbach et al.

Lukenbach et al. applied as above.

The reference is silent with respect to IRF and NED of the composition. However, since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show novel and unobvious differences between the claimed product and the product of the prior art (i.e., that the sunscreen compositions of the prior art do not possess the same material and functional characteristics of the claimed sunscreen compositions).

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15. Claims 9-11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wenker.

Wenker applied as above.

The reference is silent with respect to pH, SPF, IRF and NED of the composition. However, since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show novel and unobvious differences between the claimed product and the product of the prior art (i.e., that the compositions of the prior art do not possess the same material and functional characteristics of the claimed compositions).

Conclusion

16. No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (703) 306-4541. The examiner can normally be reached on Monday to Friday from 9 to 5.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

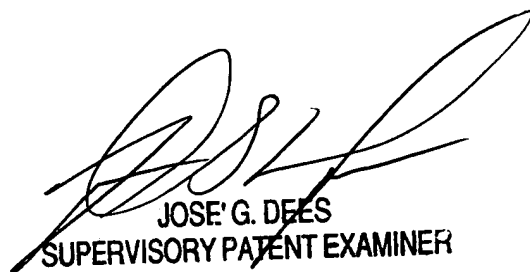
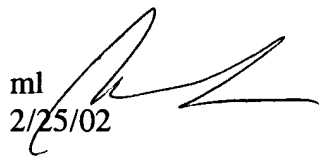
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JOSE G. DEES
SUPERVISORY PATENT EXAMINER

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